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Improvements in Stage of Change Correlate to Changes in Dietary Intake and Clinical Outcomes in a 5-year Lifestyle Intervention in Young High-Risk Sri Lankans.

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Background

It is clear lifestyle intervention is central to the prevention of type 2 diabetes (T2D) and the metabolic syndrome.^{1,2} The success of lifestyle change lies in altering several behaviours including decreasing calorie and saturated fat intake; and increasing dietary fibre and physical activity.^{1,2} In the Finnish Diabetes Prevention Study, the relative risk of T2D reduced with each additional behaviour changed.³

The traditional approach to behaviour change has often been dogmatic and education-based, with the practitioner advising the patient on appropriate action to take.⁴ However, this approach assumes that the patient is already motivated to make the changes suggested.⁵ The transtheoretical model (TTM) of behaviour change postulates that individuals are at different stages of readiness to adopt a new behaviour.⁶ It is also suggested that providing instruction to an individual in the pre-contemplation stage (the individual is not intending to change in the foreseeable future) is thought to be ineffective.⁶ For this reason previous lifestyle prevention programs have included only individuals who are ready to change.^{7,8} However, providing “stage-matched” individualised interventions tailored to a subject's individual stage of behaviour change is thought to be more effective than a single cross-population intervention.⁹ The objectives of this approach are that 1) individuals move forward through the stages of change, and 2) movement through the stages of change is associated with positive changes in health behaviours. The efficacy of “stage-matched” personalized assessment and advice has been demonstrated in people with T2D,^{10,11} hypertension,¹² and cardiovascular disease (CVD).¹³

However, the evidence is not completely consistent. Both the implementation and assessment of behaviour change programs which aim to alter food intake can be particularly challenging

due to the plural nature of dietary change.^{14,15} For example, in contrast to smoking cessation programs focussed on a singular behaviour, dietary change may include decreasing saturated fat intake, increasing fruit and vegetable intake and decreasing portion sizes. Therefore, examining progression through the stages of change and the relationship between stage of change and lifestyle behaviours requires a study with sufficient statistical power to assess changes in individual dietary components.¹⁵

Frequent follow-up visits (more than once a month, face-to-face contact during the first three months) are thought to be most effective at engendering lasting behaviour change,¹⁶ but recidivism is a common occurrence in lifestyle interventions.^{17,18} The majority of TTM-based behaviour-change programs include follow-up data of only up to one year.¹⁹⁻²² Long-term follow-up is important to determine whether a stage-matched approach can alter dietary behaviours over time.

Therefore, in this large scale study, we aimed to examine progression through the stages of change as defined by the TTM and to examine how readiness to change relates to healthful dietary changes over a 4-year follow-up in a developing population.

Method

The design of the trial is described in full elsewhere.²³ In brief, 4683 Sri Lankan urban young males and females aged 5-40 years at high risk of metabolic syndrome were randomized to intensive lifestyle modification group or less intensive control group. The principles of the lifestyle change program, which included changes in diet and physical activity, were based upon the Indian Diabetes Prevention Program (IDPP).²⁴ Clinical and dietary data was collected at baseline, and annually up to the final follow-up. The study was given ethical approval from the Sri Lanka Medical Association Ethical Review Committee (ERC 07-010). Permission from the Ministry of Education was obtained for this study which was conducted under the Good Clinical Practice Guidelines and according to the principles expressed in the Declaration of Helsinki for clinical research. All participants provided written informed consent.

Recruitment and Participants

Inclusion criteria of the trial were first degree family history of T2D, physical inactivity, elevated BMI and raised waist circumference (WC). Exclusion criteria were subjects with no or only one identifiable risk factor and subjects with diagnosed end-points. Participants were recruited from schools and work places to include a range of educational levels including no formal education, <5 years formal education, secondary education, pre-university and higher education.²³ Following screening of 23,298 participants, 5164 were identified as being eligible for the trial of whom 4682 participants attended the baseline screening. As this study assesses the TTM of behaviour change which has not been well validated in those under 11

years,¹⁴ this study examines the data of all individuals over the age of 10 years at study recruitment (n=2637).

Peer-to-Peer Approach

The baseline and follow-up dietary advice was given by trained lifestyle interventionists. The lifestyle interventionists were recruited from the local communities and did not have a medical or nutrition background. We used this approach because such community-driven initiatives provide the community with the skills and resources to implement and continue health promotion and disease prevention programmes.²⁵ Furthermore, since our cohort was also young, with more than half of people under 18 years, we also used this peer-to-peer approach to try to develop camaraderie between the interventionist and participant, such that a mutual trust and friendship could develop.²⁶ A training manual was used according to International Diabetes Federation assessors and this was supervised by representatives from Kings College London. In total, 25 people were trained. The training was done by specialists in diet, exercise and counselling using a standardised training manual approved by the International Diabetes Federation. The training included presentations on CVD, diet, exercise, and motivational interviewing techniques; working through case studies together as a group; role-play to practice counselling skills, measuring serving sizes, and dealing with barriers to change. The initial training lasted 6 weeks. Throughout the study, lifestyle interventionists were also required to attend weekly case discussions in addition to having to make a weekly presentation on a relevant health topic to the principal investigator and head of research. This ensured the quality of advice remained consistent throughout the study.

Dietary Goals

Individualised advice was given based on the needs of the subjects. In those with a raised BMI (age and gender appropriate) advice was given to achieve a 5% weight loss and in children, the aim was to limit weight gain. For both weight management and CVD risk reduction, specific goals included avoidance of simple sugars and refined carbohydrates, reduce total fat intake (not to exceed 20 g/day), restricted consumption of saturated fat and inclusion of more fibre-rich food such as whole grains, legumes, vegetables and fruits.²⁴ In order for the advice to be delivered by people the lifestyle interventionist, a simplified exchange approach was used. A list of food groups was developed with high-energy dense (not-recommended) or low-energy dense (recommended) varieties highlighted (supplementary data). While, some of the foods in the not-recommended category are not known to have detrimental effects on CVD risk (eg, egg yolks) and others are thought to be beneficial (eg, nuts), they were included in the not-recommended lists due to their high-energy content. This approach simplified the delivery of the dietary advice, and participants were advised to make “exchanges” as opposed to “reduce intake of x”.

Stage-Matching

Due to the whole-diet approach of the intervention, a generalised construct of “readiness to make healthy dietary changes” was used (supplementary data). This approach was chosen for several reasons. Firstly, the exchange model was straight-forward for the interventionists to use in improving the diet of the participants, such that they did not require a detailed knowledge of which foods were high in fat, saturated fat, high in calories or low in fibre. For the interventionists to know which dietary behaviours belonged to which stage of change construct (ie, readiness to reduce foods high in saturated fat or high in fibre) they would need

to which food group this belonged to. Such an approach may have introduced variability in the advice given and inaccurate data collection. Secondly, while constructs specific to an individual behaviour are often the most used method to assess drivers of change, some researchers suggest that a general construct such as ‘readiness to change’ or ‘concern for one’s health’ may be preferable where multiple behaviours are modified.²⁷ Finally, there is no consensus on the ideal number of behaviours that can be modified at one time.²⁸ Our whole-diet approach was to make incremental changes in the number of recommended versus not-recommended items.

The dietary exchange advice was then provided to participants based on their stage of change (supplementary data). For example, participants in precontemplation received information such as how improving the diet by making small exchanges could reduce the risk of CVD. In contemplation, interventionists reviewed possible benefits of dietary improvement, or discussed barriers to dietary exchange. If the participant was ready and open at the pre-action stages, one or two dietary exchanges were suggested. In preparation, the interventionist and participant developed an exchange plan including how and when such exchanges should be made. In action the interventionist and participant reviewed exchanges made, and discussed strategies to cope with triggers or barriers to dietary adherence. In the maintenance stage, advice was reinforced, and participants were provided with social support strategies and problem-solving skills.

Dietary Data Collection

The interventionists collected the dietary data at each follow-up, and servings were estimated using standard serving spoons and tablespoons. Serving sizes of biscuits, dairy and beverages

were assessed using common house-hold items. All counselling and follow-up sessions took place in the clinic. If the participant was under 15 years, the parents also came along as any changes required their support and understanding.

Intensive versus Control Group

All subjects in the intensive lifestyle group had face-to-face contact four times a year to assess progress and reiterate goals. The control group received identical stage-matched advice as the intensive group but this was evaluated and reinforced annually.

Clinical Outcomes

The primary outcome of the main trial was the composite cardio-metabolic end-point of new onset T2D, impaired glucose tolerance (IGT), impaired fasting glucose (IFG), hypertension, albuminuria, renal and CVD events. Fasting plasma glucose (FPG) and a standard 2-hour 75 g oral glucose tolerance test (OGTT) were performed in adults. In those below 16 years a glucose solution of 1.75 g/kg body weight, to a maximal dose of 75 g was given following a 12-hour fast as per WHO guidelines.²⁹ Plasma glucose was measured by enzymatic colorimetry (Vitros MS 250, Ortho Clinical Diagnostics, Johnson and Johnson, Co, Rochester USA). Plasma insulin was measured using radioimmunoassay (Immulite, Siemens, Surrey, UK), The sensitivity of the assay was 4 µU/ml (<24 pmol/l) and intra with an interassay coefficient of variation <8%. Insulin resistance was calculated using the homeostasis model assessment of insulin resistance (HOMA-IR).³⁰ WC was measured using a graduated measuring tape (Seca France) with a locking device to the nearest 0.1 cm. WC was taken at the mid-point between the iliac crest and the last rib in expiration. Body weight was measured without footwear in light clothing to the nearest 100 g with an electronic weighing scale

(Seca France). Height was measured using a portable stadiometer (Seca France) and taken to the closest 0.1 cm. For this study, we consider the association of stage of change with waist circumference (WC) and body weight, as surrogate measures of change in dietary intake.

Statistics

Descriptive variables are shown as mean and standard deviation, while non-normal variables are shown as median and interquartile range. Progression through stages of change year-to-year was analysed using the Friedman test. To determine within group year-to-year changes, a series of Wilcoxon tests were carried out with a manual Bonferroni correction ($\alpha=0.05$ / number of comparisons) to control for type I error. Comparison of movement through stages of change between intervention and control groups was calculated using a Chi-squared test.

Dietary changes were calculated as the ratio of recommended: not-recommended items consumed per week. Changes in recommended and not-recommended food items per week was calculated using a paired t-test (baseline to Y1, and baseline to Y4) with a repeated measures ANOVA to test differences between the intervention and control groups.

Differences in total consumption of recommended and not-recommended items per week, and weight and waist circumference by stage of change was assessed using a one way ANOVA.

An ANCOVA with group-assignment as a covariate was used to assess the relationship between stage of change and total consumption of recommended and not-recommended food items. A Bonferroni correction was used to for multiple comparisons between stage of change.

Results

Study Participants

Baseline characteristics for all participants at baseline are shown in table 1. There were no significant differences between the intensive and control groups for baseline values.

	Intensive (n=1192)		Control (n=1445)	
Age (years)	22.8 Range: 11-42 years	(9.9)	22.8 Range: 11-42 years	(9.8)
Gender	Male: Female:	1091 (47%) 1239 (53%)	Male: Female:	1097 (47%) 1256 (53%)
Ethnicity	Sinhalese Tamil Muslim Burgher Other	2005 (86%) 36 (2%) 270 (12%) 12 (1%) 3 (0%)	Sinhalese Tamil Muslim Burgher Other	2021 (86%) 39 (2%) 271 (12%) 14 (1%) 5 (0%)
Education	No formal <5 years Secondary Pre-university Higher education	1 (0%) 61 (3%) 1165 (50%) 721 (31%) 382 (16%)	No formal <5 years Secondary Pre-university Higher education	1 (0%) 57 (2%) 1145 (49%) 726 (31%) 424 (18%)
Weight (kg)	62.4	(15.0)	62.3	(14.6)
BMI (kg/m²)	24.2	(4.4)	24.0	(4.2)
Waist (cm)	84.6	(11.3)	84.2	(11.4)
FPG (mg/dL)	90.3	(14.5)	90.3	(15.3)
2hPG (mg/dL)	109.4	(35.5)	109.7	(37.4)
HOMA-IR	2.7	(2.2)	2.8	(3.0)

Table 1: Baseline characteristics of all participants who took part in the study from 2007-

2012 in Colombo, Sri Lanka. FPG: fasting plasma glucose; 2hPG: 2-hour plasma glucose;

HOMA-IR: homeostatic model assessment for insulin resistance. Figures are mean (SD)

except where noted.

Stage of Change

Participants in the intervention and control groups both progressed through the stages of change (Intervention: $Z=-16.7$, $P<0.0001$; Control: $Z=-16.1$, $P<0.0001$). In the intervention group, 38% of people moved forwards from baseline to Y1, compared to 32% in the control group (X^2 , 2, $N = 2201$) = 9.1, $p=0.01$). By Y4, 13% of the intervention group were in

maintenance, compared to 8% of the control group ($P<0.01$) (Table 2). However, overall there were no differences between the groups in total number of individuals moving forwards from baseline with 68% in the intervention and 66% in the control group having moved forwards from baseline $X^2 (2, N = 2637) = 1.25, p=0.54$). There were no differences in stage of change progression when individuals aged less than 15 years were excluded

		Precontemplation	Contemplation	Preparation	Action	Maintenance
Baseline	I	1 (*)	308 (26)	753 (63)	72 (6)	58 (5)
	C	2 (*)	336 (23)	955 (66)	78 (5)	74 (5)
Y1	I	0	11 (*)	929 (78)	36 (3)	58 (5)
	C	1 (*)	11 (*)	1071 (74)	30 (2)	54 (4)
Y2	I	0	23 (2)	881 (74)	136 (11)	46 (4)
	C	0	42 (3)	1113 (77)	120 (8)	45 (3)
Y3	I	1 (*)	72 (6)	600 (50)	318 (27)	68 (6)
	C	1 (*)	108 (8)	861 (60)	309 (21)	45 (3)
Y4	I	0	119 (10)	535 (45)	386 (32)	152 (13)
	C	0	127 (9)	730 (51)	475 (33)	113 (8)

(Supplementary data).

Table 2: Number (%) of participants in each stage of change from baseline to Y4 in the intervention and control groups. The study took place from 2007-2012 in Colombo, Sri Lanka.

*less than 1%

Achievement of Dietary Goals

The aim of the study was to replace not-recommended food items with recommended food items, and therefore dietary data has been presented as a ratio of recommended: not-recommended items. There were significant increases from baseline to Y1 and baseline to Y4 for most dietary outcomes in the intervention group (Table 3). In the control group there were also significant increases from baseline to Y1 and Y4 in unsweetened to sweetened beverages

($P < 0.001$; $P < 0.001$) and non-starch to starchy vegetables ($P = 0.007$; $P < 0.001$) (Table 3). The intervention group had a higher ratio of recommended to non:recommended items Y1 to Y4; mainly explained by a higher ratio of brown rice versus white rice and of recommended to starchy vegetables (figure 1).

		Follow-up	Mean \pm SEM	Sig.
Intervention	Total recommended to not-recommended	B-Y1	0.45 \pm 0.09	0.000
		B-Y4	0.11 \pm 0.08	0.18
	Recommended to not-recommended fruits	B-Y1	0.67 \pm 0.42	0.11
		B-Y4	0.48 \pm 0.51	0.35
	Non-starch vegetables to starchy vegetables	B-Y1	4.75 \pm 0.98	0.000
		B-Y4	4.90 \pm 0.73	0.000
	Brown rice to white rice	B-Y1	0.84 \pm 0.12	0.000
		B-Y4	1.30 \pm 0.13	0.000
	Unsweetened to sweetened beverages	B-Y1	0.67 \pm 0.20	0.001
		B-Y4	0.80 \pm 0.17	0.000
	Low-fat to high-fat	B-Y1	0.25 \pm 0.07	0.000
		B-Y4	0.16 \pm 0.74	0.03
	Unpolished to polished carbohydrates	B-Y1	0.56 \pm 0.18	0.002
		B-Y4	0.89 \pm 0.18	0.000
Control	Total recommended to not-recommended	B-Y1	0.17 \pm 0.06	0.003
		B-Y4	0.05 \pm 0.07	0.45
	Recommended to not-recommended fruits	B-Y1	0.27 \pm 0.26	0.30
		B-Y4	0.32 \pm 0.38	0.41
	Non-starch vegetables to starchy vegetables	B-Y1	2.48 \pm 0.92	0.007
		B-Y4	3.20 \pm 0.63	0.000
	Brown rice to white rice	B-Y1	0.23 \pm 0.14	0.08
		B-Y4	0.76 \pm 0.14	0.000
	Unsweetened to sweetened beverages	B-Y1	0.69 \pm 0.18	0.000
		B-Y4	0.85 \pm 0.15	0.000
	Low-fat to high-fat	B-Y1	0.14 \pm 0.06	0.039
		B-Y4	0.07 \pm 0.06	0.24
	Unpolished to polished carbohydrates	B-Y1	0.01 \pm 0.16	0.93
		B-Y4	0.50 \pm 0.16	0.002

Table 3: Mean change in ratio of recommended to non:recommended food items between

baseline (B) and year 1 (Y1) and year 4 (Y4) in the intervention and control groups. At Y1

there were completed diet and stage of change assessments from 1192 participants in the intervention and 1445 in the control groups. At Y4 there were 1086 in the intervention and 1320 in the control group. The study took place from 2007-2012 in Colombo, Sri Lanka.

Relationship Between Stage of Change and Overall Dietary Recommendations

The consumption of recommended items was positively related, and consumption of not-recommended items was negatively related to stage of change each year across the entire cohort ($p > 0.0001$) (Figure 2). These relationships were significant in both the control and intervention groups (data not shown). Similarly, there were significant relationships between stage of change and ratio of recommended to non recommended items; unpolished:polished carbohydrates; brown rice: white rice; non-starch:starchy vegetables and low-fat:high fat items from baseline to Y4 across the entire cohort.

Relationship Between Stage of Change and Clinical Measures

Stage of change at baseline or Y1 was not related to weight or waist circumference at Y4. Participants in preparation, action and maintenance from Y2 to Y4 had an attenuated increase in weight and waist circumference, compared to precontemplation and contemplation. Specifically, at Y2, participants in contemplation had a significantly greater increase in weight at Y4 compared to action ($P = 0.04$) and maintenance ($P = 0.02$). Participants in contemplation at Y3 had a significantly greater increase in weight and waist circumference at Y4 compared to preparation (weight: $P < 0.0001$; waist: 0.012), action (weight: $P < 0.0001$; waist: $P < 0.0001$), and maintenance (weight: $P < 0.0001$; waist: $P < 0.0001$). Stage of change at

Y4 was also significantly related to increases in weight gain and waist circumference (Figure 3).

Discussion

In this large-scale primary prevention study we are able to show significant increases through stage of change over a 4-year period which related to positive changes in dietary behaviours throughout each year of the study and key clinical outcomes at the final follow up.

Interestingly, the control group which received only annual stage-matched advice also demonstrated increases through the stage of change and improvements in dietary intake.

The aim of stage-matched interventions is to progress from a state of inaction to a state of action, alongside corresponding dietary changes.^{9,14} A previous study on South Asians in Scotland -with a similar proportion of people at each stage of change at baseline as our present study- found that 50% of subjects increased their stage of change at 6 months, and a common assumption is that individuals will regress thereafter.³¹ We demonstrate that readiness to change was not only sustained beyond one year in this study, improvements were seen up to 5 years, such that by year 4 close to 70% of participants in the intervention group had moved forwards from baseline, upwards from 40% at year 1. However, we cannot suggest that improvements would be sustained beyond 5 years following termination of the study. Of note, other studies have not found significant progress through stages of change. For example, Verheijden et al³² measured readiness to change for fat intake specifically and found that 67% of people showed no movement between 0-6 months, which remained at 62% at 12 months. However, due to a lack of power, theirs and other studies³³ have combined pre-contemplation and contemplation into preaction, and preparation, action and maintenance

into post-preparation. A strength of our study therefore lies in the statistical power to analyse the individual groups separately.

Alongside movement through stages of change, we also found significant increases in the ratio of unrefined:to refined carbohydrates, non-starch:starchy vegetables and low:fat to high-fat products at the Y1 follow-up which were sustained at Y4. Although, self-reported dietary data has well-documented limitations, we demonstrate that such changes had a measurable impact on waist circumference and body weight at the final follow-up visit. A number of smaller interventional studies have examined specific nutrients such as fat or calcium, or singular food items such as fruits or vegetables. In general these data support the effectiveness of stage-matched interventions in reducing dietary fat and increasing fruit and vegetable intake.^{19,26,27} However, none of these studies found any effect on body weight, or examined or demonstrated an effect on meaningful clinical outcomes.^{19,32,33} The dietary advice in this study was based on commonly consumed food sources amongst the local Sri Lankan population, and an exchange model of 35 food groups was used to give simple, easy-to-translate advice. At baseline, rice intake represented 18% of the 35 food groups consumed. Since 100g of white rice has approximately 20kcal more than 100g wholegrain rice, while the calorie differential between low-fat and high-fat products,³⁴ and between non-starch and starchy vegetables is even greater, even small changes in the consumption of these food choices will aggregate to have a pronounced effect on the overall diet. This supports data from a multiple behaviour intervention in overweight US adults, where weight loss was seen at 24-month follow-up.³⁵

Given the intensive nature of the intervention group in this study, with 3-monthly contact, we had expected that the individuals in the intensive group would progress through the stages

more quickly than those in the control group. However, the differences were not significant by Y4. We believe the design of the program may explain why there was close alignment between the control and intervention groups. Participants were recruited from the same household/school/office, where potentially one person's changes in the intensive group influenced a control individual. Similarly, we did not find a relationship between missing one to two counselling sessions a year in the intervention group and changes in staging (data not shown). We believe that high-profile research projects such as DIABRISK-SL enhance awareness of T2D and associated risks amongst all the study subjects, their friends and families. Therefore, while this may have confounded the analysis for this research study, in public-health terms, the transfer of public health messages across a population may be more cost-effective.

This study adds valuable data to the literature on motivation and stage-matching in an ethnic population for which data is scarce. We demonstrate that at baseline the vast majority of people in this study were in preparation which is comparable to a study on South Asians in Scotland³¹ which found 56% of people in preparation at baseline, compared to 30% in pre-and contemplation, and 12% in action or maintenance. Similarly, in that study the percentage of people in action increased from 12 to 39% from baseline to 6 months, and the percent of people in maintenance increased from 1-17%. They also found significant improvements in reducing salt intake, and eating fried meat snacks. We corroborate and extend these findings by demonstrating improvements up to 5 years in a larger population. Therefore, culturally appropriate interventions can increase motivation and improve dietary behaviours in ethnic populations.

We do acknowledge some limitations in this study. Firstly, the control group also included a stage-matching approach, albeit at yearly intervals. Therefore we cannot make a true assessment of whether stage-matched is better than other merely individualised approaches. However, we do think the large sample size and long-follow up is a strength demonstrating that motivation level can be increased in a similar intervention and is associated with improvements with dietary behaviours and key clinical outcomes. By demonstrating clear and consistent associations between both dietary advice and clinical outcomes at each stage of change we also demonstrate the validity of staging in behavioural interventions. While advice was given using locally recognised portion sizes to ensure consistency between research sites in this study, we did not use standard portion sizes, and the food frequency questionnaire (which was not validated) did not provide a reliable indicator of total calorie intake. However, we think the strength of our approach lies in its easy-to-translate advice, which was effective across a large, relatively young population. Finally, the TTM also includes decisional balance, self-efficacy and processes of change as the transitional determinants. However, we only considered the stage of change in this study and cannot provide any insight into the other constructs of the TTM.

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References

1. Orchard TJ, Temprosa M, Goldberg R, Haffner S, Ratner R, Marcovina S, Fowler S; Diabetes Prevention Program Research Group. The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial. *Ann Intern Med.* 2005;142(8):611-9.
2. Lindström J, Louheranta A, Mannelin M, Rastas M, Salminen V, Eriksson J, Uusitupa M, Tuomilehto J; Finnish Diabetes Prevention Study Group. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. *Diabetes Care.* 2003;26(12):3230-6.
3. Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M; Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med.* 2001;344(18):1343-50.
4. Kravitz RL, Hays RD, Sherbourne CD, DiMatteo MR, Rogers WH, Ordway L, Greenfield S.
Recall of recommendations and adherence to advice among patients with chronic medical conditions. *Arch Intern Med.* 1993;153(16):1869-78.
5. Guise BJ. Behavioral medicine strategies for heart disease prevention: the example of smoking cessation. *Prev Cardiol.* 2000 Winter;3(1):10-15.
6. Prochaska JO, Redding C, Evers K. The Transtheoretical Model of behaviour change. In: Glanz K, Lewis FM, Rimer BK, editors. *Health Behaviour and Health Education: Theory, Research and Practice.* 2nd ed. San Francisco, Calif: Jossey-Bass; 1997. pp. 60-84.
7. DPP Group Diabetes Prevention Program Research Group. The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care.* 1999;22(4):623-34.
8. Look AHEAD Research Group. The look AHEAD study: A description of the lifestyle intervention and the evidence supporting it. *Obesity.* 2007a;14(5):737-752.
9. Prochaska JO, Velicer WF, Rossi JS, Goldstein MG, Marcus BH, Rakowski W, Fiore C, Harlow LL, Redding CA, Rosenbloom D, et al. Stages of change and decisional balance for 12 problem behaviors. *Health Psychol.* 1994;13(1):39-46.
10. Clark M, Hampson SE, Avery L, Simpson R. Effects of a tailored lifestyle self-management intervention in patients with type 2 diabetes. *Br J Health Psychol.* 2004;9(Pt 3):365-79.
11. Jalilian M, Moeini B, Hazavehei SM, Beigi AM, Sharifirad G, Nodeh FH. Physical activity stage-matched intervention: Promoting metabolic control in type 2 diabetes. *J Educ Health Promot.* 2013 Apr 30;2:18.
12. Friedberg JP, Rodriguez MA, Watsula ME, Lin I, Wylie-Rosett J, Allegrante JP, Lipsitz SR, Natarajan S. Effectiveness of a tailored behavioral intervention to improve hypertension control: primary outcomes of a randomized controlled trial. *Hypertension.* 2015;65(2):440-6.

13. van der Veen J, Bakx C, van den Hoogen H, Verheijden M, van den Bosch W, van Weel C, van Staveren W. Stage-matched nutrition guidance for patients at elevated risk for cardiovascular disease: a randomized intervention study in family practice. *J Fam Pract.* 2002;51(9):751-8.
14. Spencer L, Wharton C, Moyle S, Adams T. The transtheoretical model as applied to dietary behaviour and outcomes. *Nutr Res Rev.* 2007;20(1):46-73.
15. Naylor PJ, Simmonds G, Riddoch C, Velleman G, Turton P. Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. *Health Educ Res.* 1999;14(5):653-66.
16. Carvajal R, Wadden TA, Tsai AG, Peck K, Moran CH. Managing obesity in primary care practice: a narrative review. *Ann N Y Acad Sci.* 2013;1281:191-206.
17. Look AHEAD Research Group, Wing RR. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. *Arch Intern Med.* 2010;170(17):1566-75.
18. Appel LJ, Brands MW, Daniels SR, Karanja N, Elmer PJ, Sacks FM; American Heart Association. Dietary approaches to prevent and treat hypertension: a scientific statement from the American Heart Association. *Hypertension.* 2006;47(2):296-308.
19. Steptoe A, Perkins-Porras L, McKay C, Rink E, Hilton S, Cappuccio FP. Behavioural counselling to increase consumption of fruit and vegetables in low income adults: randomised trial. *BMJ.* 2003;326(7394):855.
20. Mau MK, Glanz K, Severino R, Grove JS, Johnson B, Curb JD. Mediators of lifestyle behavior change in Native Hawaiians: initial findings from the Native Hawaiian Diabetes Intervention Program. *Diabetes Care.* 2001;24(10):1770-5.
21. Prochaska JO, Velicer WF, Redding C, Rossi JS, Goldstein M, DePue J, Greene GW, Rossi SR, Sun X, Fava JL, Laforge R, Rakowski W, Plummer BA. Stage-based expert systems to guide a population of primary care patients to quit smoking, eat healthier, prevent skin cancer, and receive regular mammograms. *Prev Med.* 2005;41(2):406-16.
22. Auslander W, Haire-Joshu D, Houston C, Rhee CW, Williams JH. A controlled evaluation of staging dietary patterns to reduce the risk of diabetes in African-American women. *Diabetes Care.* 2002;25(5):809-14.
23. Wijesuriya M, Gulliford M, Vasantharajah L, Viberti G, Gnudi L, Karalliedde J. DIABRISK-SL prevention of cardio-metabolic disease with life style modification in young urban Sri Lankan's--study protocol for a randomized controlled trial. *Trials.* 2011 Sep 26;12:209. doi: 10.1186/1745-6215-12-209.
24. Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V; Indian Diabetes Prevention Programme (IDPP). The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia.* 2006;49(2):289-97.
25. Hennessey Lavery S, Smith ML, Esparza AA, Hrushow A, Moore M, Reed DF. The community action model: a community-driven model designed to address disparities in health. *Am J Public Health.* 2005;95(4):611-6.

26. Shinitzky HE, Kub J. The art of motivating behavior change: the use of motivational interviewing to promote health. *Public Health Nursing*. 2001;18(3):178-85.
27. Koshy P, Mackenzie M, Leslie W, Lean M, Hankey C. Eating the elephant whole or in slices: views of participants in a smoking cessation intervention trial on multiple behaviour changes as sequential or concurrent tasks. *BMC Public Health*. 2012 Jul 3;12:500.
28. Nigg CR, Allegrante JP, Ory M: Theory-comparison and multiple-behavior research: common themes advancing health behavior research. *Health Educ Res*. 2002, 17 (5): 670-679.
29. World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Report of a WHO Consultation. Part 1: Diagnosis and Classification of Diabetes Mellitus. Geneva. WHO Department of Noncommunicable Disease Surveillance; 1999. pp. 1–59.
30. Matthews DR, Hosker JP, Rudenski AS, Naylor BA, Treacher DF, Turner RK. Homeostasis model assessment: insulin resistance and β -cell function from fasting plasma glucose and insulin concentration in man. *Diabetologia*. 1985;28:412–419.
31. Mathews G, Alexander J, Rahemtulla T, Bhopal R. Impact of a cardiovascular risk control project for South Asians (Khush Dil) on motivation, behaviour, obesity, blood pressure and lipids. *J Public Health (Oxf)*. 2007;29(4):388-97.
32. Verheijden MW, Van der Veen JE, Bakx JC, Akkermans RP, Van den Hoogen HJ, Van Staveren WA, Van Weel C. Stage-matched nutrition guidance: stages of change and fat consumption in Dutch patients at elevated cardiovascular risk. *J Nutr Educ Behav*. 2004;36(5):228-37.
33. Finckenor M, Byrd-Bredbenner C. Nutrition intervention group program based on preaction-stage-oriented change processes of the Transtheoretical Model promotes long-term reduction in dietary fat intake. *J Am Diet Assoc*. 2000;100(3):335-42.
34. Food Standard Agency. McCance and Widdowson's the composition of foods. Institute of Food Research, Public Health England, editors. Royal Society of Chemistry; 2014 Sep 24.
35. Johnson SS, Paiva AL, Cummins CO, Johnson JL, Dymant SJ, Wright JA, Prochaska JO, Prochaska JM, Sherman K. Transtheoretical model-based multiple behavior intervention for weight management: effectiveness on a population basis. *Prev Med*. 2008;46(3):238-46.

Figure 1: Mean difference in ratio of the different recommended to non:recommended food items between the intervention (I) and control (C) groups at baseline (B), year 1 (Y1), year 2 (Y2), year 3 (Y3) and year 4 (Y4). P values indicate differences between intervention and control group. The study took place from 2007-2012 in Colombo, Sri Lanka.

* $P \leq 0.05$

** $P \leq 0.01$

*** $P \leq 0.001$

Figure 2: Number of total recommended and not-recommended items in each stage of change at baseline (B), year 1 (Y1), year 2 (Y2), year 3 (Y3) and year 4 (Y4) amongst the entire cohort. P values were adjusted for multiple comparisons and reflect differences between stage of change. PC= precontemplation; C=contemplation; P=preparation; A=action; M=maintenance. Note: at B, Y1 and Y3, there were <5 subjects, and therefore statistics were not performed. The study took place from 2007-2012 in Colombo, Sri Lanka.

* $P \leq 0.05$

** $P \leq 0.01$

*** $P \leq 0.001$

Figure 3: Mean changes in weight (kg) and waist circumference (cm) from baseline to Y4 by stage of change amongst the entire cohort. P values were adjusted for multiple comparisons and reflect differences between stage of change. C=contemplation; P=preparation; A=action; M=maintenance. The study took place from 2007-2012 in Colombo, Sri Lanka.

* $P \leq 0.05$

** $P \leq 0.01$

*** $P \leq 0.001$

ACCEPTED MANUSCRIPT

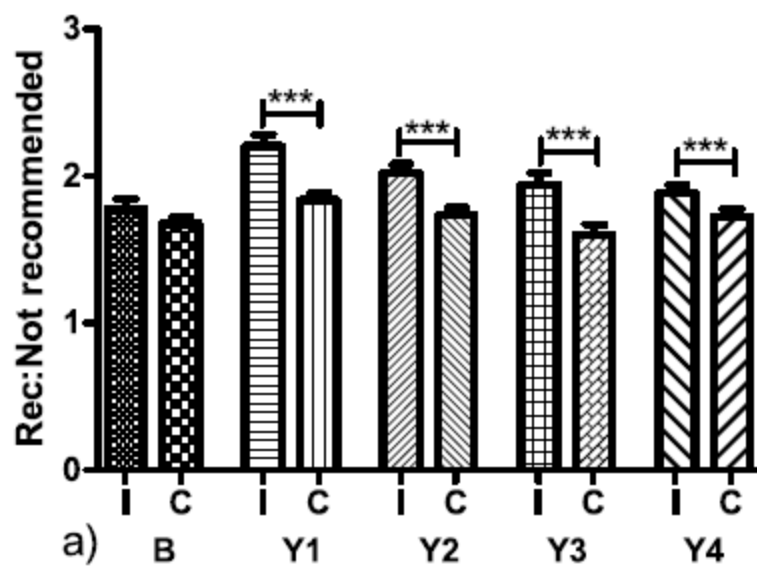


Figure 1a

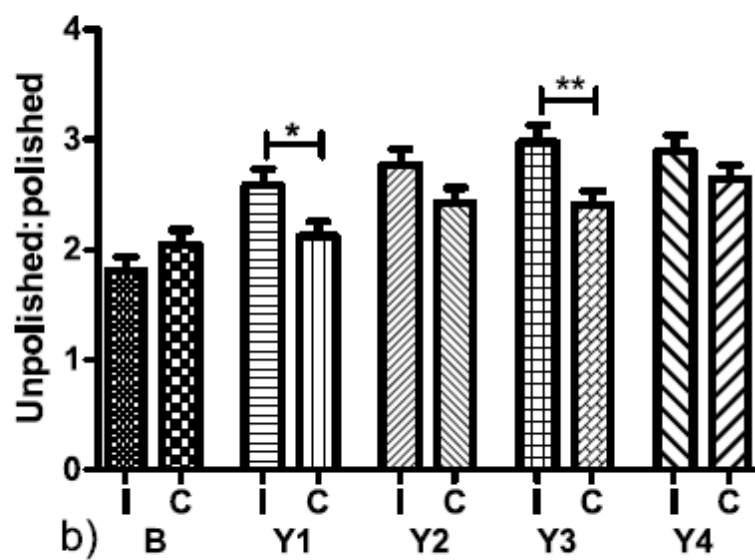


Figure 1b

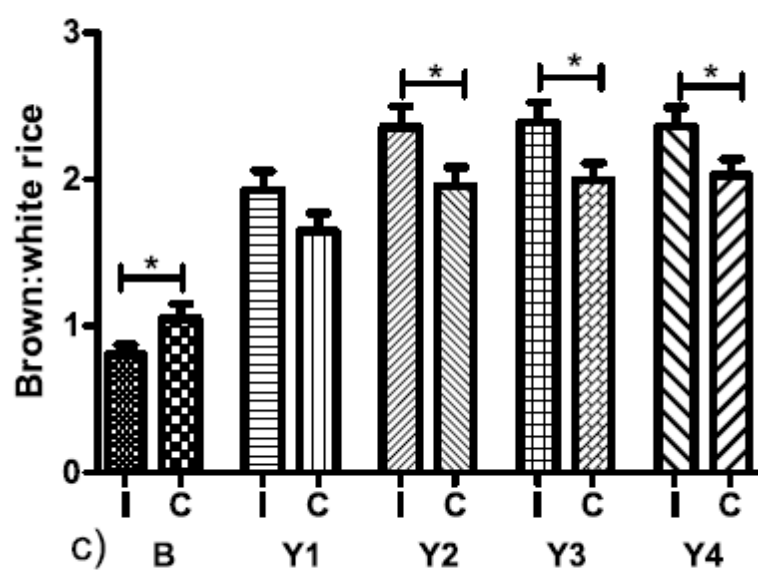


Figure 1c

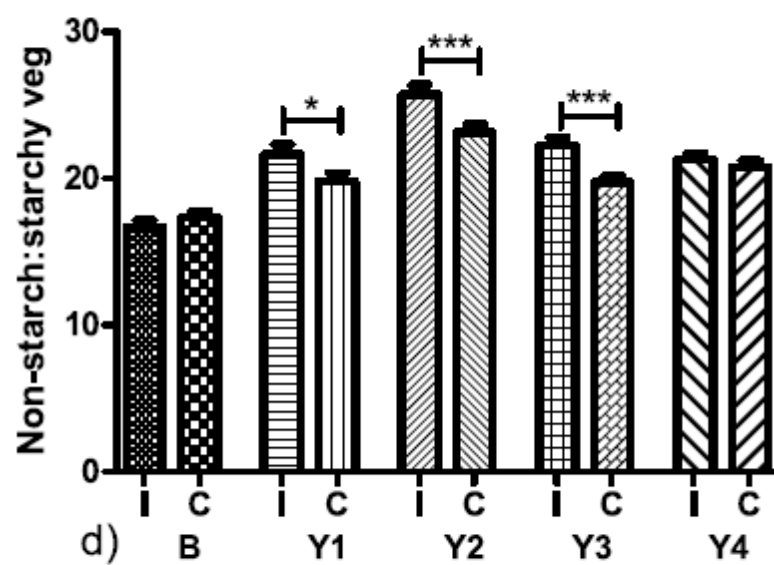


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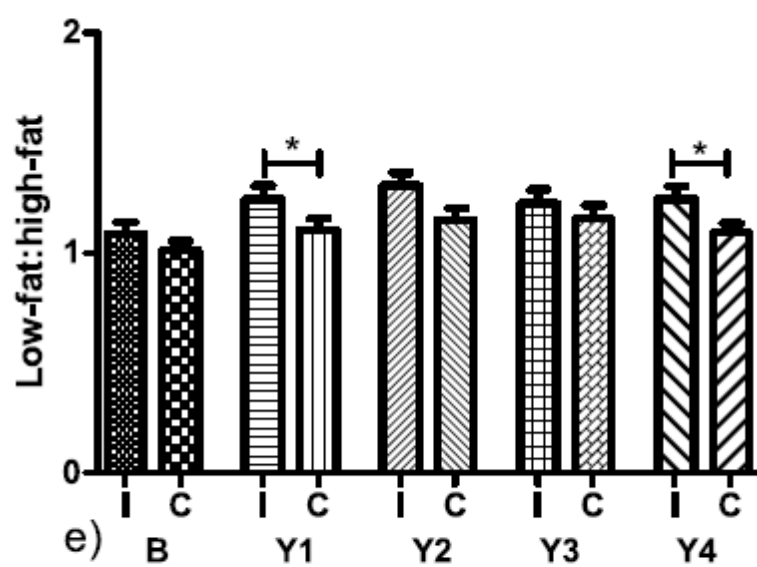


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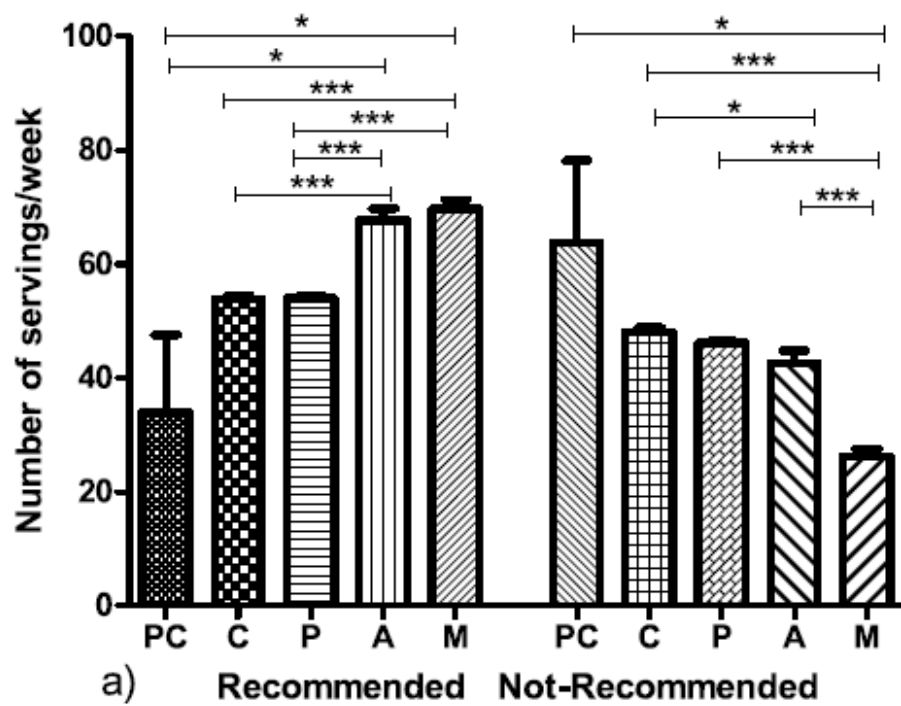


Figure 2a

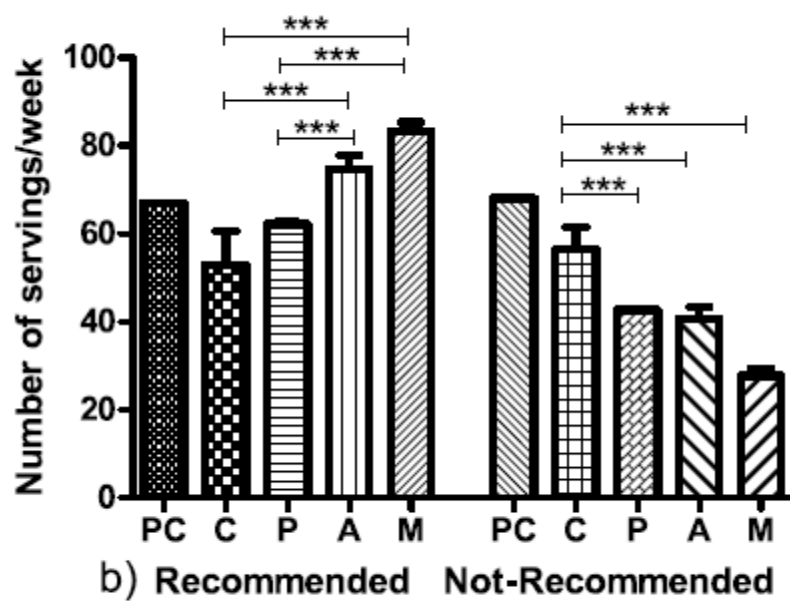


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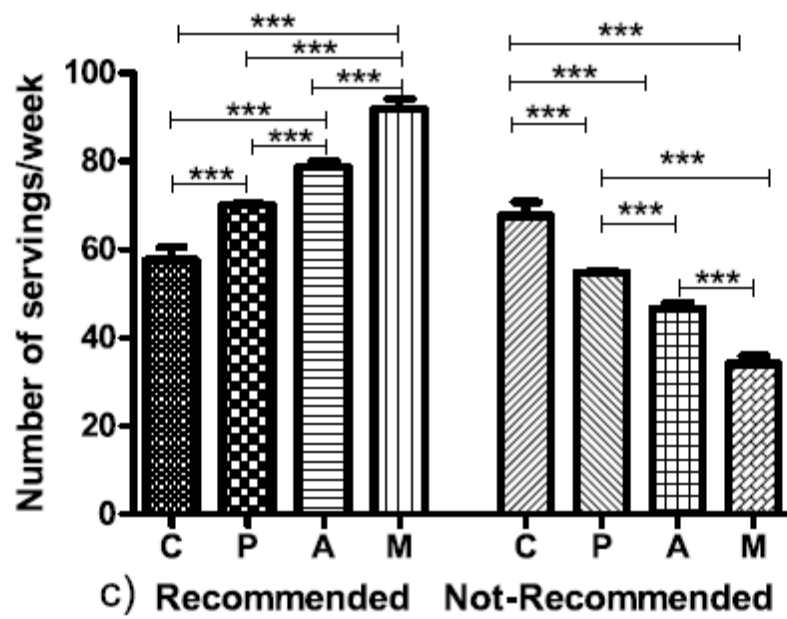


Figure 2c



Figure 2d

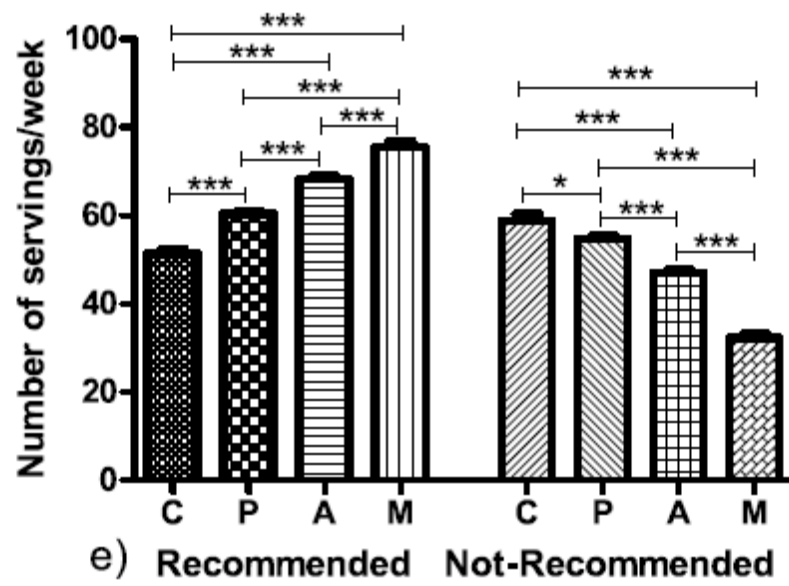


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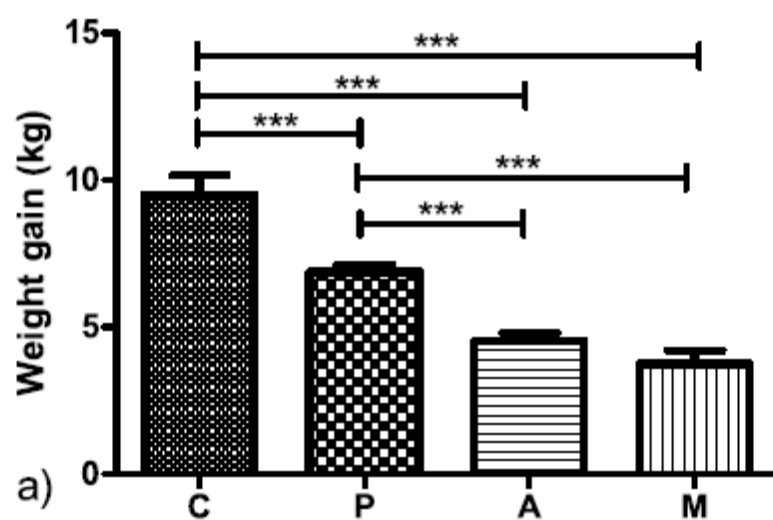


Figure 3a

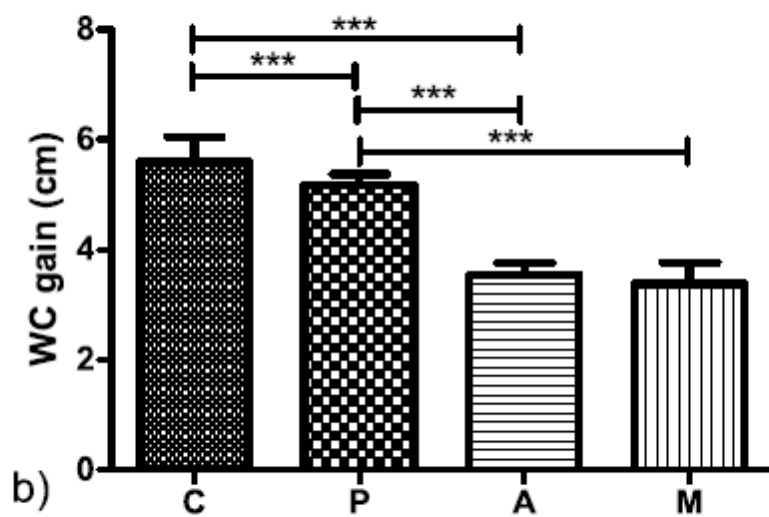


Figure 3b

Highlights

- The transtheoretical model was used in a large primary prevention study in Sri Lanka.
- Both intervention and control groups progress through stages of change over 5 years.
- Readiness to change is associated with dietary intake.
- Readiness to change also associated with waist circumference and body weight.